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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,492	12/04/2001	Rango Dietrich	24826	6447

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,492	DIETRICH ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2 and 4-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1, 2 and 4-47 are pending. Claims 1, 2 and 4-47 are subject to an Election/Restriction requirement.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4-10, 21-32 and 45-47, drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units, classified in class 424, subclass 484.

Group II, claim(s) 11-15, 18-20 and 33-44, drawn to an active compound unit comprising an acid-labile active compound (no pharmaceutical excipient) and a process for the production of an active compound unit in the form of a microsphere classified in class 424, subclass 489.

Group III, claim(s) 16 and 17, drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound, classified in class 424, subclass 489.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I-III are drawn to distinct formulations and methods that contain different components and features.

Inventions of Group I and Group II are unrelated. Group I (claims 1, 2, 4-10, 21-32 & 45-47) is drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units. Group II (claims 11-15, 18-20 & 33-44) is drawn to an active compound unit comprising an acid-labile active compound and a process for the production of an active compound unit in the form of a microsphere. The invention of Group I requires the incorporation of pharmaceutical excipients, whereas the invention of Group II does not require excipients. Therefore, Groups I and II have different issues regarding patentability and enablement. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden on the Examiner.

Inventions of Group I and Group III are unrelated. Group I (claims 1, 2, 4-10, 21-32 & 45-47) is drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units. Group III (claims 16 & 17) is drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound. The invention of Group I is directed to product claims requiring the incorporation of pharmaceutical excipients, whereas the invention of Group III are process and product claims, which do not recite any pharmaceutical excipients.

Therefore, Groups I and III have different issues regarding patentability and enablement. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden on the Examiner.

Inventions of Group II and Group I are unrelated. Group II (claims 11-15, 18-20 & 33-44) is drawn to an active compound unit comprising an acid-labile active compound and a process for the production of an active compound unit in the form of a microsphere. Group I (claims 1, 2, 4-10, 21-32 & 45-47) is drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units. The invention of Group II does not require excipients, whereas the invention of Group I requires the incorporation of pharmaceutical excipients. Therefore, Groups II and I have different issues regarding patentability and enablement. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden on the Examiner.

Inventions of Group II and Group III are unrelated. Group II (claims 11-15, 18-20 & 33-44) is drawn to an active compound unit comprising an acid-labile active compound and a process for the production of an active compound unit in the form of a microsphere. Group III (claims 16 & 17) is drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound. Group II is directed to different methods, requiring distinct process steps than those claimed in Group III claims. The different inventions would require completely different searches in both patent and non-patent databases,

and there is no expectation that the searches would be coextensive. This creates an undue burdensome search.

Inventions of Group III and Group I are unrelated. Group III (claims 16 & 17) is drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound. Group I (claims 1, 2, 4-10, 21-32 & 45-47) is drawn to an administration form for acid-labile active compounds comprising pharmaceutical excipients and multiple individual active compound units. Group III are process and product claims, which do not recite any pharmaceutical excipients, whereas, the invention of Group I is directed to product claims requiring the incorporation of pharmaceutical excipients. Therefore, Groups III and I have different issues regarding patentability and enablement. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue search burden on the Examiner.

Inventions of Group III and Group II are unrelated. Group III (claims 16 & 17) is drawn to a process for the production of an active compound unit in the form of a microsphere comprising an acid-labile active compound. Group II (claims 11-15, 18-20 & 33-44) is drawn to an active compound unit comprising an acid-labile active compound and a process for the production of an active compound unit in the form of a microsphere. Group III are process and product claims, directed to different processes, requiring distinct process steps than those claimed in Group II claims. The different inventions would require completely different searches in both patent and non-patent databases, and there is no expectation that the searches would be coextensive. This creates an undue burdensome search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III and so forth, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Note: If Applicant chooses to elect Group I (claims 1, 2, 4-10, 21-32 & 45-47), then the following election of species is further required:

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows:

Election of Administration Form:

(a) Suspensions

(b) Gels, Suppositories

(c) Tablets, Effervescent Tablets, Rapidly Disintegrating Tablets

(d) Coated Tablets, Sugar-Coated Tablets, Multi-component Tablets

(e) Powders in sachets

(f) Capsules

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

January 13, 2005

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SUPERVISORY PATENT EXAMINER
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